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(54) Abstract Title
A bronchial ventilation device

(57) A bronchial ventilation assembly which enables selective ventilation of a patient's lungs comprises a ventilation device having first and second bronchial tubes 6, 8 for insertion into the left and right bronchi respectively, and a tracheal tube 4 which includes first and second tracheal tube sections which communicate with the first and second bronchial tubes respectively. The configuration of the device can be changed between an in-use configuration in which bronchial tubes splay outwardly as shown, and an insertion configuration in which the bronchial tubes are closed together for insertion of the device into a patient's trachea. The assembly includes an insertion instrument for changing the configuration of the device between its in-use configuration and its insertion configuration. This instrument may be a sleeve 40 slidable along the tube 4 to hold the bronchial tubes together against their resilient tendency to splay apart, during insertion. Alternatively, it may comprise a drawstring, Figures 5 and 6.

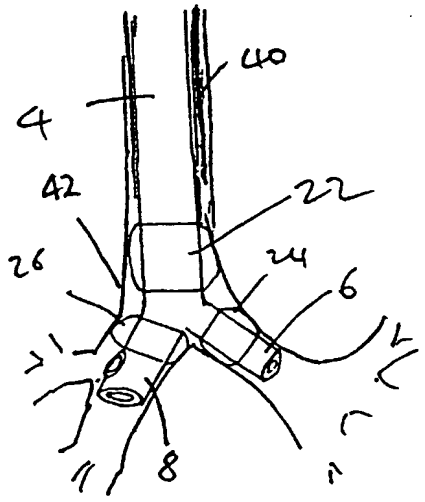


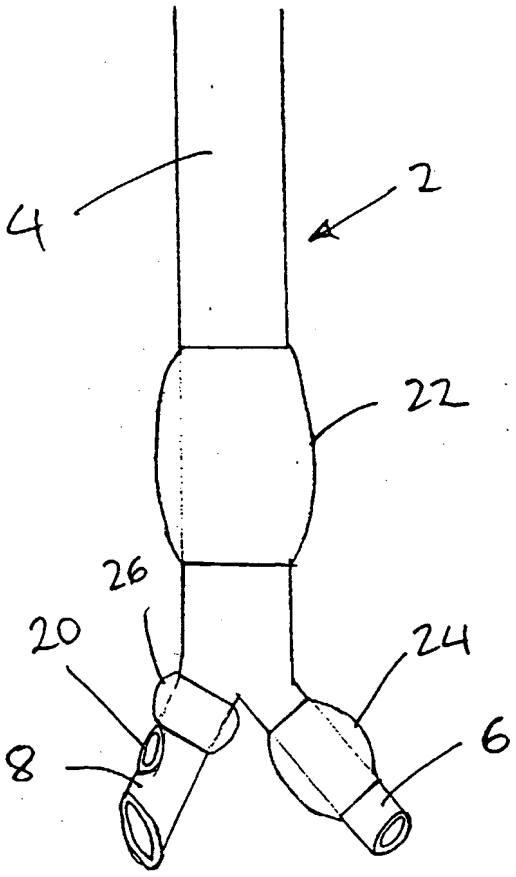
Figure 4.

GB 2 373 445 A

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

This print takes account of replacement documents submitted after the date of filing to enable the application to comply with the requirements of the Patents Rules 1995

Figure 1



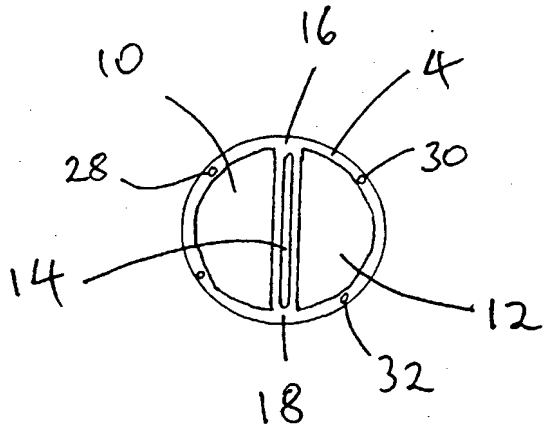


Figure 2.

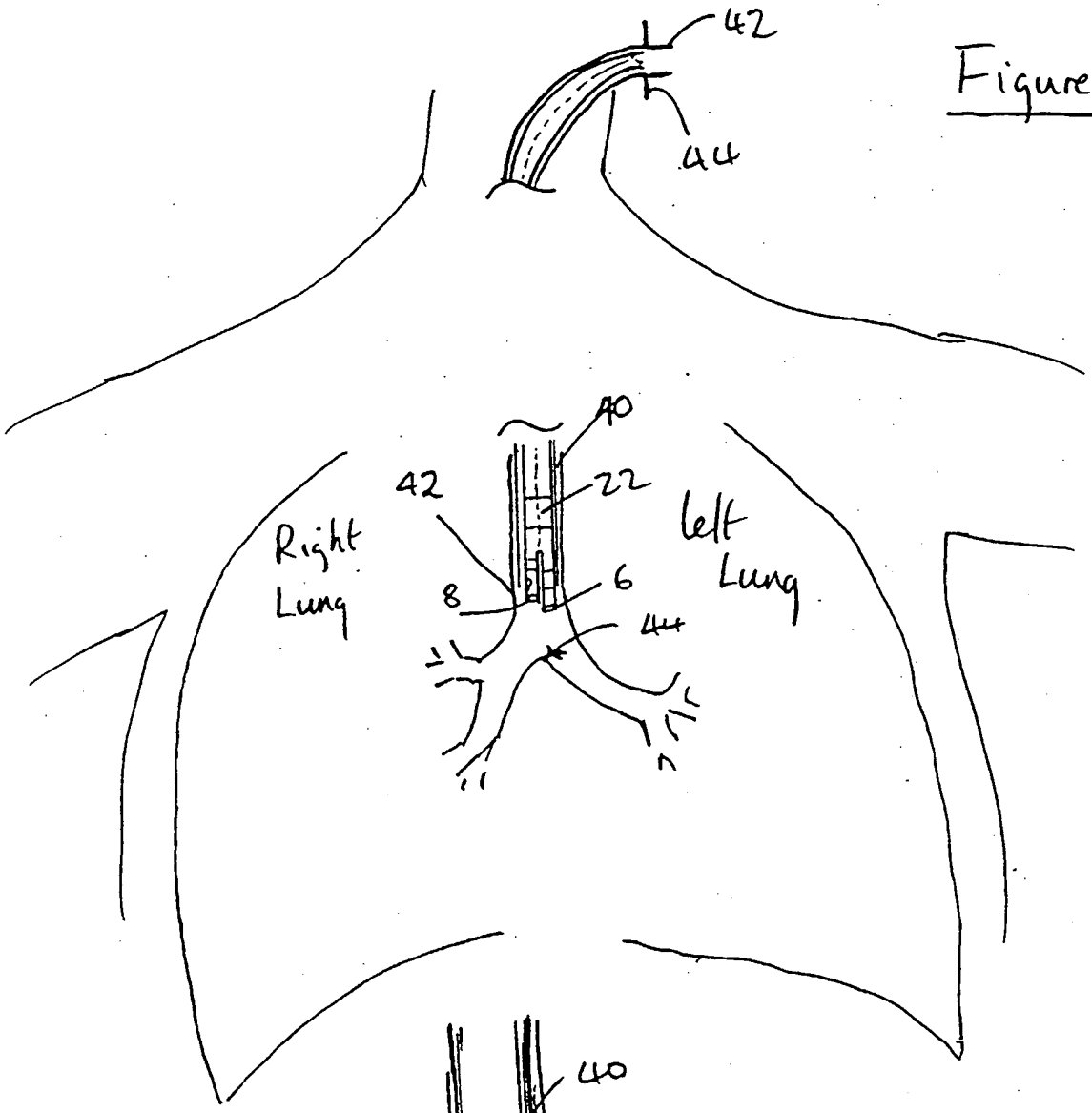


Figure 3

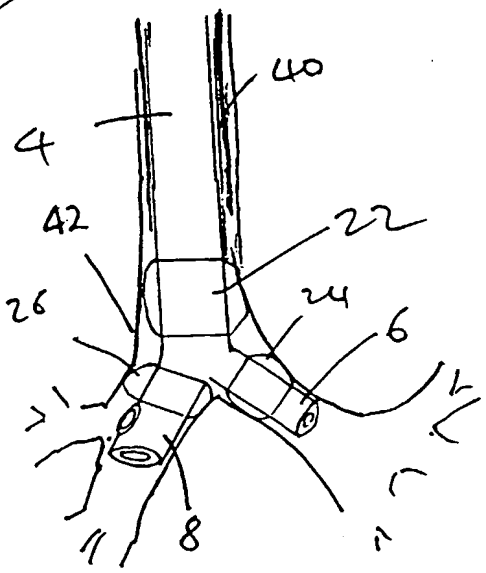


Figure 4.

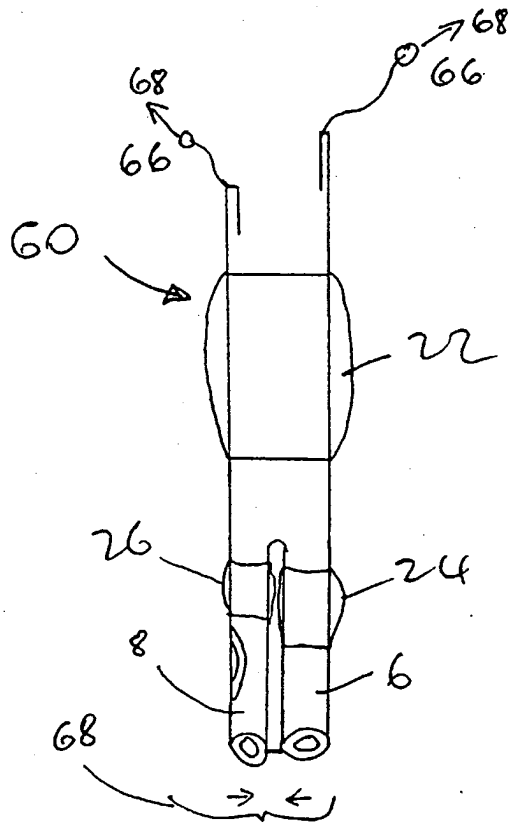


Fig 5

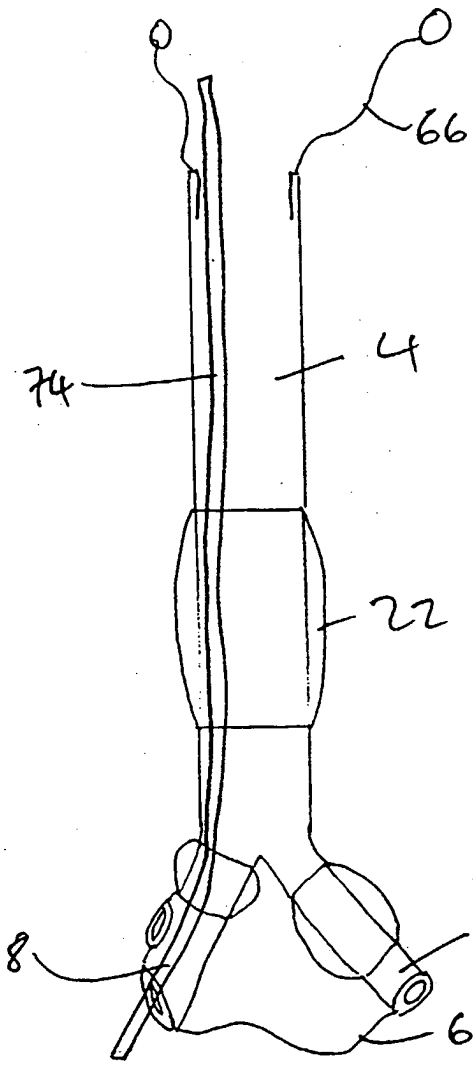


FIG 6

A BRONCHIAL VENTILATION ASSEMBLY

This invention relates to a bronchial ventilation assembly which comprises a ventilation device to facilitate selective ventilation of a patient's bronchi, and an insertion instrument which enables the device to be advanced through a patient's trachea.

Bronchial ventilation devices are used by anaesthetists to control selective lung ventilation through a patient's left or right main bronchi. This can be desirable for example when surgery is performed on the patient's chest cavity, or when one lung has been damaged. It can also be desirable when a lung has an abscess which is to be drained, and can reduce the risk of transmission of infection from one lung to the other. Known devices include tubes with cuff seals which enable one bronchus to be isolated from the other; a seal can be formed with such devices by supplying an inflation fluid to the cuff. Existing devices can include two lumens, in which one lumen extends into one of the bronchi and the other lumen terminates above the carina for ventilation of the other lung.

Selective bronchial ventilation can also be achieved by selectively blocking one bronchus by means of a tube with a cuff seal, in which the seal can be inflated when positioned in the bronchus, occluding the bronchus against flow of air.

Such devices are advanced through the trachea after insertion orally or through a tracheotomy stoma. Accurate location of the end of the device in the bronchus is important, in particular so that the user can be sure that a reliable seal can be formed allowing isolation of one bronchus from the other. It is preferred that the engagement of the device in the bronchus should be positive and secure to reduce the likelihood of the device being dislodged.

It is known to incorporate a hook to engage the carina at the junction between the bronchi. Known devices are configured so that the seals and lumen openings are properly located relative to the trachea and the bronchi when the hook has engaged the carina. A disadvantage of such devices is that the hook can damage the patient's airways as the device is advanced through the trachea. It can also be difficult to engage the hook with the

patient's carina in some cases, leading to failure of seals between the device and the patient's tissue. Difficulties with locating the hook on the carina can also lead to the lumen being advanced into the wrong bronchus. Reducing the frequency of inaccurate location of known devices can require the use of complicated and expensive equipment such as fibre optic bronchoscopes or x-ray imaging equipment (which can require incorporation of x-ray marker material in the device).

The present invention provides a ventilation assembly which comprises a ventilation device having a tracheal portion and separate tubes for location in the bronchi, and an insertion instrument for changing the configuration of the device between its in-use configuration and its insertion configuration.

Accordingly, the invention provides a bronchial ventilation assembly which comprises (a) a ventilation device having first and second bronchial tubes for insertion into the left and right bronchi respectively, and a tracheal portion which includes first and second tracheal tube sections which communicate with the first and second bronchial tubes respectively, the configuration of the device being capable of being changed between an in-use configuration in which bronchial tubes splay outwardly, and an insertion configuration in which the bronchial tubes are closed together for insertion of the device into a patient's trachea, and (b) an insertion instrument for changing the configuration of the device between its in-use configuration and its insertion configuration.

The assembly of the present invention has the advantage that the bronchial tubes can be configured so as to extend into the bronchi and so that the device engages the carina securely. The provision of separate tubes for the two bronchi can make it easier for the user (for example, surgeon, anaesthetist, nurse, or paramedic) to locate a bronchial tube reliably in a selected bronchus. With known devices which have a single bronchial tube (optionally with a carina hook), the user is required to manipulate the device as it is advanced through the patient's trachea so that the bronchial tube ends in the desired bronchus. Such known devices have to be sufficiently stiff so that they are capable of being manipulated as they are advanced in the trachea, and can include stiffening elements (for example in the form of a length of wire) to provide the desired stiffness. Even with

these features, anatomical differences between patients can make it difficult for the user to locate the device as required quickly. The device of the present invention with separate bronchial tubes has the advantage that it corresponds more closely to a patient's anatomy which can mean that proper location of the device can be clearly recognisable by feel by the user.

The relative ease with which the ventilation device can be located, in particular with reduced need for extensive manipulation by the user, can mean that the device can be made less rigid than with known devices. This can mean that a patient's airway is less likely to be damaged as the device is advanced through the trachea. A patient might therefore be less likely to suffer adverse cough or other respiratory complications after use of the device of the invention compared with previously known devices.

The engagement of the device with the carina can also reduce the risk of a ventilation device becoming dislodged after it has been located.

These advantages of the ventilation device which flow from the provision of separate bronchial tubes are made possible by the use of the insertion instrument which provides control over the configuration of the ventilation device between an insertion configuration in which the bronchial tubes are closed together and an in-use configuration in which the bronchial tubes diverge. This enables the advantages of the invention that arise from the separate bronchial tubes to be obtained even with a device on which the in-use configuration would otherwise make it difficult to advance the device through a patient's airway.

Preferably, the device includes a resilient material so that changing the configuration of the device from a first one of the in-use configuration and the insertion configuration to the other of the two configurations involves deforming the device resiliently, and changing the configuration to a first one of the in-use configuration and the insertion configuration from the other of the two configurations involves allowing the device to relax. For example, the device is deformed resiliently to its in-use configuration from its insertion configuration by increasing the angle between the bronchial tubes. More preferably, the device is deformed

resiliently from its in-use configuration to its insertion configuration by reducing the angle between the bronchial tubes.

A preferred form of insertion instrument comprises an insertion sleeve which the device can fit into when the bronchial tubes are forced together (especially by resilient deformation), which can be retracted relative to the device (for example by withdrawing the sleeve or by advancing the device from the distal end of the sleeve) to allow the device to adopt its in-use configuration in which the bronchial tubes diverge. Suitable insertion sleeves can be made from low friction plastics materials, for example, certain polyamides or polyesters. It can be preferable for one or both of the external surface of the device and the internal surface of the sleeve to be treated so as to reduce frictional forces between them. For example, one or each surface might be coated with a material which dissolves partially when exposed to an aqueous solution, or with a lubricant gel such as that sold under the trade mark KY Jelly.

It can be preferred for the insertion sleeve to have a line of weakness formed in it which facilitates splitting and retraction of the sleeve, prior to removal. Preferably, the line of weakness extends to the proximal end of the insertion sleeve, or to the distal end of the insertion sleeve, or both. When the line of weakness extends to the proximal end of the sleeve, splitting the sleeve can be initiated at the proximal end and the split can extend along the sleeve towards the distal end. When the line of weakness extends to the distal end, a split in the sleeve that is initiated at or towards the proximal end can propagate to the distal end so that the sleeve is open at the distal end. Preferably, the insertion has grip portions at the proximal end on opposite sides of the line of weakness, which can be gripped by a user to apply force across the line of weakness to cause the sleeve to split.

It is an advantage of the use of the insertion sleeve that it can be used to ventilate a patient, for example when the patient requires urgent ventilation and it is not possible to advance a selected ventilation device to a desired location. To facilitate such urgent ventilation, the ventilation sleeve can be provided on its proximal end with a connector formation which is configured to engage a corresponding connector on ventilation apparatus so that the tubular

sleeve of the insertion instrument can be used to ventilate the patient. Suitable connectors which are known for this use have a diameter of 15 mm.

The tubes of the ventilation device can be used to provide a flow path for breathing gas to pass into one or other bronchus during ventilation of that bronchus. When the ventilation device is used to achieve selective ventilation by blocking one of the bronchi against flow of breathing gas, the tubes can be used to supply gas to a cuff to inflate the cuff so that it blocks the bronchus. In this arrangement, the bronchial tube will have a relatively small cross-sectional area so that breathing gas can flow around the outside of the tube, consistent with being able to supply gas to the blocking seals in order to inflate them satisfactorily. One or each of the tubes can be closed at its distal end, with its purpose then being to enable inflation of the cuff on the tube so as to block the bronchus. The tube can be open at its end and include a separate lumen (or conduit) for inflation of the cuff, the open-ended lumen being for insertion of another instrument (for example a bronchoscope) or to allow passage of small quantities of breathing gas (generally subject to control by means of a valve at around the proximal end of the tube). When the device is intended to be used in this way, the device will preferably include two sealing cuffs to enable respective seals to be formed between (a) the first bronchial tube and the left bronchus, and (b) the second bronchial tube and the right bronchus. The bronchial tubes, and also the tracheal tube sections, will then generally be kept relative small in cross-sectional area in order to minimise obstruction of the patient's natural airway to flow of breathing gas.

In another aspect, the invention provides a bronchial ventilation assembly which comprises (a) a ventilation device comprising a tracheal section which includes first and second tracheal tube sections which can communicate a patient's first and second bronchi respectively (in which the ventilation device could have one or two bronchial tubes), and (b) an insertion instrument comprising a tubular sleeve which can be introduced into the patient's trachea and can then receive the ventilation device to guide it towards its in-use position. Preferably, the insertion instrument having towards its proximal end a connector formation which is configured to engage a corresponding connector on ventilation apparatus so that the tubular sleeve of the insertion instrument can be used to ventilate the patient.

Preferably, the assembly includes a guide element, especially with a rounded end, which can be inserted into the patient's trachea to guide the insertion instrument into the trachea by sleeving the sleeve of the insertion instrument over the guide element. Examples of suitable guide elements are known as trocars. Suitable guide elements can have a bore extending through them for use with guide wires which can be used to control the location to which a guide element, and ultimately a ventilation device, is directed.

The assembly of this aspect of the invention can be provided with other features of the assembly discussed above; for example, the connector formation can have grip portions on the insertion sleeve at the proximal end on opposite sides of a line of weakness, which can be gripped by a user to apply force across the sleeve to cause it to split.

The insertion sleeve can be curved when viewed along the medial-lateral axis in such a way as to conform to the anatomical configuration of a patient's upper airways when the sleeve (generally with a ventilation device within it) has been advanced to an in-use position in the airway.

In another form, the insertion instrument can comprise a drawstring which extends to about the ends of the bronchial tubes which can be tensioned from the proximal end of the device. For example, the drawstring might extend between the bronchial tubes at or towards their ends and, when tensioned, force the bronchial tubes inwardly towards one another. The drawstring might extend to the ends of the bronchial tubes along the outside facing edges thereof and, when tensioned, cause the bronchial tubes to diverge.

Preferably, the device has a bore extending along at least part of its length, the drawstring extending within the bore. It will generally be preferred for the device to have two bores extending along it, with separate drawstrings for each of the bronchial tubes. For example, when the drawstring is tensioned to cause the bronchial tubes to diverge, separate drawstrings can be provided in respective bores and attached to respective bronchial tubes at or towards their ends. Each of the drawstrings can be tensioned to cause the respective bronchial tubes to move outwardly. When the drawstring is used to force the bronchial tubes towards one another for advancement through the trachea, it will generally be

preferred for the drawstring to extend between the bronchial tubes at or towards their ends and to extend from the ends of the bronchial tubes to the proximal end of the device through bores in the device so that the drawstring can be tensioned at each of its ends by drawing it through the bores. When the device shown has been advanced to the vicinity of the carina, tension on the drawstring can be relaxed allowing the bronchial tubes to diverge. Continued advancement of the device into the trachea causes the bronchial tubes to pass into the bronchi, with the closure line resting loosely over the carina.

The bores in the device for the drawstring can be formed conveniently when the device is formed by extrusion.

The reduced need for manipulation during location of the device in a patient's trachea can give rise to the advantage that the device can be made with thinner walls than with known devices. This can enable the device of to provide less resistance to air flow. It can also facilitate the placement of other apparatus in the device, for example suction catheters, without causing unacceptably high resistance to air flow.

A further advantage of the reduced likelihood of trauma that arises from the use of more flexible materials is that the ventilation device can be left *in situ* within a patient's airway for longer periods than is the case with known devices. This provides the possibility of using the device in situations other than during anaesthesia and surgery. For example, the device might be used for ventilation of a patient who is sedated during recovery from surgery or from trauma, or on an intensive care unit.

The ability to isolate and ventilate either of a patient's lungs has the advantage of reduced inventory for hospitals: the device of the present invention avoids the need to stock separate components for isolation of the left and right lungs respectively.

The positive engagement of the two bronchial tubes of the device of the invention with a patient's carina can enable each of the bronchial tubes to be kept shorter than in known devices which have just one bronchial tube. Such short tubes can provide satisfactory ventilation of the individual bronchi. They can enable access to be gained to structures

close to the junction between each bronchus and the trachea, for example for ventilation of the right upper lobe bronchus or to drain collected fluid from it.

If a user needs to confirm that the ventilation device has been properly located in a patient's trachea, its position might be confirmed using conventional auscultation techniques, for example a stethoscope. It might be determined by observing differential chest movements, especially after the formation of seals using the cuffs on the device. Bronchoscopic or x-ray techniques can be used to verify that the bronchial tubes have been properly located in the respective bronchi.

The provision of separate bronchial tubes in the ventilation device has the further advantage that both bronchi can be accessed by other components which are advanced into the lung via the tracheal tube (for example a suction catheter) which can be advanced along the appropriate bronchial tube. This is in contrast to known devices with just one bronchial tube which can only be used reliably to advance a suction catheter tube or other apparatus into the bronchus in which the bronchial tube is located.

The arrangement of the tracheal and bronchial tubes will generally be arranged so as to provide a comfortable fit in the patient's airways. The angle between the bronchial tubes will generally be at least about 55°, preferably at least about 65°, for example about 70°. The angle between the right bronchial tube and the tracheal tube will preferably be greater than the angle between the left bronchial tube and the tracheal tube. Preferably, the difference between the two said angles is at least about 15°, for example about 20°.

The tracheal tube will generally have a rounded cross-section, especially substantially circular. Preferably, the cross-sections of the first and second tracheal tube sections are approximately D-shaped, the tube sections being arranged so that the rounded walls face outwardly and provide the outer walls of the tracheal tube. The flattened walls of the D-shaped tracheal tube sections can then provide a web which extends along the tracheal tube, generally approximately along the centre of the tube so as to divide it into tube sections of approximately equal sizes. The web along the centre of the tracheal tube can help to support the tracheal tube against collapse when exposed to transverse compressive

forces or other forces which might tend to cause the tube to kink. The contribution to the structural integrity of the device from the dividing web can allow the wall thickness of the curved outer walls to be kept small. This can mean that the resistance to flow of air through the tube can be minimised.

Preferably, the device has a bore in the tracheal portion between the flat walls of the tracheal tube sections. The bore can enable the tracheal portion to be split so as to separate the tracheal tube sections which can then provide the bronchial tubes. The device can therefore provide a continuous passage for flow of breathed gas without any discontinuity at the junction between the tracheal portion and the bronchial tubes. This enables resistance to airflow at the junction due to such a discontinuity to be avoided.

It is preferred for the cross-sections of the tracheal tube sections and the bronchial tubes to be approximately the same, at least at the junction between the tracheal tube and the bronchial tubes. Preferably, the cross-sections of the first and second bronchial tubes, and especially also the tracheal tube sections, are approximately D-shaped, at least at the junction between the tracheal tube and the bronchial tubes. However, the bronchial tubes can be formed into a different shape towards their free ends; for example, bronchial tubes that have a D-shaped cross-section can be formed (for example at an elevated temperature) to make their cross-section more round, especially closer to circular.

Preferably, each tracheal tube section and its corresponding bronchial tube are formed continuously as single components so that there is no discontinuity between them which could provide resistance to airflow. Preferably, the tracheal tube sections are formed as a single component so that the bronchial tubes are formed by splitting a two chamber tube along part of its length. However, in an alternative arrangement, the tracheal portion can be formed by attaching two tracheal tube sections together, for example by means of an adhesive or by heating the material of the tube sections locally to cause it to fuse, or mechanically such as by binding, for example using a wound tape.

Preferably, the ventilation device includes at least one sealing cuff which enables a seal to be formed between (a) the tracheal tube and the trachea, (b) the first bronchial tube and the

left bronchus, or (c) the second bronchial tube and the right bronchus, to enable isolation and separate ventilation of the two bronchi. The device can provide the advantage of isolation of the separate bronchi when it has sealing cuffs on just one or two of the tracheal tube and the two bronchial tubes. For example, sealing cuffs might be provided on each of the bronchial tubes, or on the tracheal tube and the first bronchial tube or the second bronchial tube. Preferably, however, the device has sealing cuffs on each of the tracheal tube, and the first and second bronchial tubes so that seals can be made as desired between any of the trachea and the tracheal tube, the first bronchial tube and the left bronchus, and the second bronchial tube and the right bronchus. An advantage of providing sealing cuffs on the tracheal tube and on both of the bronchial tubes is that the device can be used to isolate the individual bronchi even in the event of one of the sealing cuffs becoming damaged, or one of the seals provided by the sealing cuffs failing, for example as a result of the sealing cuff being dislodged within the trachea or the bronchus.

When the device includes a sealing cuff on the right bronchial tube, it is preferred that the cuff is arranged on the right bronchial tube so as to reduce obstruction of the right upper lobe bronchus. The sealing cuff can have a substantially constant depth across the tube and be inclined to the axis of the tube. Alternatively or in addition, the sealing cuff might have a reduced depth in the vicinity of the right upper lobe bronchus. It is also possible for obstruction of the right upper lobe bronchus to be avoided by trimming the bronchial tube short of the bronchus, preferably on a plane that is inclined to the axis of the right main bronchus.

Preferably, the sealing cuff is inflatable and the device includes conduit means for supplying an inflation fluid to the cuff. The inflation fluid can be a gas or a liquid. An example of a suitable inflation fluid is air, especially as pumped with a syringe or a manually squeezable bladder. An alternative fluid might be a saline solution, which can be introduced using a syringe. Preferably, the conduit means comprises separate conduits for supplying inflation fluid separately to each of the sealing cuffs. The conduit means can be a part of a structure which is separate from the tracheal tube and the bronchial tubes. Preferably, however, the conduit means comprises one or more bores that is formed in the

wall of the tracheal tube. Such a bore can be formed in the tube wall by a process such as extrusion.

The device in the assembly of the invention can be configured for oral introduction or through a tracheotomy stoma. The length of the tracheal tube will be greater when the device is intended for oral introduction than for when the device is intended for introduction through a tracheotomy stoma, generally as known in existing bronchial ventilation devices. The device can include a flange for fixation to the patient's neck when it is intended for introduction through a tracheotomy stoma.

The device of the invention can be provided in a range of sizes. When breathing gas is to be supplied through the bronchial tubes, it is preferred that the cross-sectional area of each of the bronchial tubes is at least about 15 mm^2. Devices that are suitable for use by adult patients can have a bronchial tube cross-sectional area of at least about 22 mm^2, or at least about 25 mm^2, or larger such as at least about 35 mm^2 or more.

When the device of the invention is configured for supply of breathing gas naturally through the patient's trachea and selected bronchus, with flow of breathing gas to the other bronchus being closed by means of a blocking seal provided by an inflated cuff, the bronchial tubes, and also the tracheal tube sections, will then generally be kept relative small in cross-sectional area in order to minimise obstruction of the patient's natural airway to flow of breathing gas, consistent with being able to supply gas to the blocking seals in order to inflate them satisfactorily.

The assembly of the invention can be used in open thoracic surgery such as for example a lobectomy, closed thoracoscopic procedures such as lung resection, treatment of pleural disease and sympathectomy. It can also be used in oesophageal surgery and thoracic aortic surgery. It can be used for ventilation of patients on an intensive care unit as discussed above, in particular because of the reduced risk of trauma in a patient's tissues because of the use of more flexible materials that those used hitherto. Features of the device which is incorporated into the assembly of the invention are disclosed in the patent application filed with the present application which claims priority from UK patent application no.

0030475.8 and features which are disclosed in that document can be incorporated in the device referred to in this specification.

Embodiments of the present invention will now be described, by way of example, with reference to the accompanying drawings in which:

Figure 1 is a side view of a ventilation device according to the invention.

Figure 2 is a cross-sectional view of the tracheal tube of the device shown in Figure 1.

Figure 3 is a front view of a patient's thoracic region (with the trachea exposed) showing a device as shown in Figure 1 during placement using a first introducer.

Figure 4 is another front view of the patient's thoracic region, showing the device in place in the patient's bronchi.

Figure 5 is a side view of another device with a second introducer.

Figure 6 is a side view of a device as shown in Figure 5 in place in the configuration in which it might be used in a patient's bronchi.

Referring to the drawings, Figures 1 and 2 show a ventilation device 2 which comprises a tracheal tube 4 and first and second bronchial tubes 6, 8. The device is formed from a polymeric material such as polyvinyl chloride by extrusion. As shown in Figure 2, the trachea tube comprises first and second tube sections 10, 12. Each of the tube sections is substantially D-shaped when viewed in cross-section. A narrow bore 14 is provided between the facing flat walls of the tube sections. The bronchial tubes are provided by slitting the narrow webs 16, 18 which extend between the facing flat walls of the trachea tube sections in the extrusion, and by trimming the webs from the slit extrusion. Preferably, the bronchial tubes are reformed while heated to an elevated temperature so that their cross-section becomes more rounded. Preferably, the ends of the bronchial tubes are rounded to minimise risk of snagging on airway tissue.

The bronchial tubes are made to diverge, as shown in Figure 1, by heating the device to a temperature slightly below the temperature at which the polymer loses its form, and then forming the device to the desired configuration in which it is held while the device is allowed to cool.

The cross-sectional area of each of the trachea tube sections, and therefore also of the bronchial tube sections, is about 30 mm^2. Smaller device might be appropriate for smaller patients, including children.

The second bronchial tube 8 is intended to be placed in the right bronchus in a patient. It has an opening 20 in its side wall for ventilation of the right upper lobe bronchus. Obstruction of the right upper lobe bronchus can also be avoided by making the right bronchial tube short, especially by trimming it inclined to the axis of the bronchial tube.

Inflatable sealing cuffs 22, 24, 26 are provided on each of the bronchial tubes and on the tracheal tube. Each of the sealing cuffs is formed from a thin sheet of a polymeric material such as a polyester, which is bonded to the respective tube around its periphery. Each of the cuffs can be inflated into contact with the trachea or the bronchus in which it is located when in use, to form a seal. The seals can be inflated by means of a fluid, especially air which is admitted using a manually operated pump or a syringe as is known. Bores 28, 30, 32 are provided in the extrusion for the inflation fluid to be supplied to the sealing cuffs (see Figure 2).

Figure 3 shows the device described above within an insertion sleeve 40 which forces the bronchial tubes 6, 8 towards one another so that the cross-section of the device in the region of the bronchial tubes is similar to that of the tracheal tube. This allows the device to be advanced through the patient's trachea 42. A lubricant can be provided between the sleeve and the device, for example a lubricant such as a typical sterile gel. The insertion sleeve has a 15 mm diameter connector 43 at its proximal end which can engage a corresponding connector on ventilation apparatus so that the sleeve can be used to ventilate the patient's lungs. The sleeve also has laterally extending wings 44 which can be gripped to apply transverse force to the sleeve to cause it to split along its length.

As shown in Figure 4, the device of the invention can be restored to its in-use configuration after it and the insertion sleeve 40 have been advanced sufficiently through a patient's trachea. This will generally be appropriate when the distal end is close to the carina 44. The sleeve can be withdrawn by the user, or the device advanced through the sleeve so that at least the bronchial tubes and possibly also a part of the tracheal tube extend from it. Removal of the sleeve can be facilitated by making it splittable. For example, the sleeve might have a line of weakness extending along its length along which it can be split. Splitting the sleeve can be initiated proximally by the user.

Figure 5 shows a device 60 constructed generally as described above with reference to Figures 1 and 2. The device includes two additional bores in the extrusion, similar to the bores 28, 30, 32 shown in Figure 2, for a drawstring 66. The line extends continuously from the proximal end of the tracheal tube through one of the bores, across the end of distal ends of the bronchial tubes 6, 8, and through the other of the bores to the proximal end of the tracheal tube. The line can then be manipulated by the user.

In the configuration shown in Figure 5, the bronchial tubes are forced together so that the device can be advanced through a patient's trachea. This is achieved by applying tension to the drawstring 66, as indicated by the arrows 68.

When the device shown in Figure 5 has been advanced to the vicinity of the carina 69, tension on the drawstring 66 can be relaxed allowing the bronchial tubes 6, 8 to diverge. Continued advancement of the device into the trachea causes the bronchial tubes to pass into the bronchi, the drawstring 66 resting over the carina. Fluid can then be supplied to the sealing cuffs 22, 24, 26 through the bores in the tracheal tube to cause the cuffs to inflate to form seals to the patient's tissue. The patient's bronchi can then be ventilated selectively. The bronchial tubes can also be used to direct a suction catheter tube 74 reliably into the left or right bronchus, for example into the right bronchus as shown in Figure 6.

In an alternative construction, a drawstring can extend along the ventilation device and be fixed to the ends of the bronchial tubes. The tubes are configured so that they tend towards

a configuration in which they are close together. The device is made from a resilient material so that the configuration of the device can be changed to one in which the tubes diverge. Changing the configuration of the device is achieved by applying tension to the drawstring; this can be done when the device has been advanced through the patient's airway until the end of the device is in the vicinity of the carina. Tension applied to the drawstring causes the bronchial tubes to diverge so that they can be advanced into the bronchi.

CLAIMS:

1. A bronchial ventilation assembly which comprises (a) a ventilation device having first and second bronchial tubes for insertion into the left and right bronchi respectively, and a tracheal tube which includes first and second tracheal tube sections which communicate with the first and second bronchial tubes respectively, the configuration of the device being capable of being changed between an in-use configuration in which bronchial tubes splay outwardly, and an insertion configuration in which the bronchial tubes are closed together for insertion of the device into a patient's trachea, and (b) an insertion instrument for changing the configuration of the device between its in-use configuration and its insertion configuration.

2. An assembly as claimed in claim 1, in which the device includes a resilient material so that changing the configuration of the device from a first one of the in-use configuration and the insertion configuration to the other of the two configurations involves deforming the device resiliently, and changing the configuration to a first one of the in-use configuration and the insertion configuration from the other of the two configurations involves allowing the device to relax.

3. An assembly as claimed in claim 2, in which the device is deformed resiliently from its in-use configuration to its insertion configuration by reducing the angle between the bronchial tubes.

4. An assembly as claimed in claim 3, in which the insertion instrument comprises an insertion sleeve which the device can fit into when the bronchial tubes are forced together, which can be retracted to allow the device to adopt its in-use configuration in which the bronchial tubes diverge.

5. An assembly as claimed in claim 4, in which the insertion sleeve has a line of weakness formed in it which facilitates splitting and retraction of the sleeve.

6. An assembly as claimed in claim 5, in which the line of weakness extends to the distal end of the insertion sleeve.

7. An assembly as claimed in claim 5, in which the line of weakness extends to the proximal end of the insertion sleeve.

8. An assembly as claimed in claim 7, which includes grip portions on the insertion sleeve at the proximal end on opposite sides of the line of weakness, which can be gripped by a user to apply force across the line of weakness to cause the sleeve to split.

9. An assembly as claimed in claim 3, in which the insertion instrument comprises a drawstring which extends to about the ends of the bronchial tubes which can be tensioned from the proximal end of the device.

10. An assembly as claimed in claim 9, in which the device has a bore extending along at least part of its length, the drawstring extending within the bore.

11. An assembly as claimed in claim 1, in which the cross-sections of the first and second tracheal tube sections are approximately D-shaped, the tube sections being arranged so that the rounded walls face outwardly and provide the outer walls of the tracheal tube.

12. An assembly as claimed in claim 1, in which the device includes sealing cuffs which enable seals to be formed between at least two of (a) the tracheal tube and the trachea, (b) the first bronchial tube and the left bronchus, and (c) the second bronchial tube and the right bronchus, to enable isolation and separate ventilation of the two bronchi.

13. A bronchial ventilation assembly which comprises (a) a ventilation device comprising a tracheal tube which includes first and second tracheal tube sections which can communicate a patient's first and second bronchi respectively, and (b) an insertion instrument comprising a tubular sleeve which can be introduced into the patient's trachea and can then receive the ventilation device to guide it towards its in-use position.

14. An assembly as claimed in claim 13, in which the insertion instrument has towards its proximal end a connector formation which is configured to engage a corresponding connector on ventilation apparatus so that the tubular sleeve of the insertion instrument can be used to ventilate the patient.

15. An assembly as claimed in claim 13, which includes a guide element which can be inserted into the patient's trachea to guide the insertion instrument into the trachea by sleeving the sleeve of the insertion instrument over the guide element.

16. An assembly as claimed in claim 15, in which the guide element has a rounded distal end.

17. An assembly as claimed in claim 13, in which the connector formation has grip portions on the insertion sleeve at the proximal end on opposite sides of a line of weakness, which can be gripped by a user to apply force across the sleeve to cause it to split.

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Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T): A5R(RGEX)

Int Cl (Ed.7): A61M 16/04, 25/01, 25/092

Other: ONLINE: EPODOC, PAJ, WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
Y	GB 2098485 A	(DRAGERWERK) lines 15-34 of page 2	9, 10
Y	US 5309906	(LABOMBARD) lines 23-56 of column 2	11
X, Y	US 4309994	(GRUNWALD) line 58 of column 3 to line 18 of column 4	X: 1-3 Y: 9, 10
X, Y	US 4248224	(JONES) lines 13-40 of column 3	X: 1-4, 13 Y: 11

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
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